

therefore lacks patentable utility. The invention is directed toward a Recogin protein vaccine to prevent or treat cancer. The specification fails to establish the utility of the claimed vaccine for preventing the development of cancer or treating cancer in humans..." Office Action dated 12/22/1993 (Paper # 6) at 5. This rejection was maintained in the Office Action dated 9/12/1994 (Paper # 10) and in the Advisory Action of 2/22/95 (Paper # 14).

On December 23, 1994, the Commissioner of Patents and Trademarks, Bruce Lehman, issued proposed "Guidelines for Examination of Applications for Compliance with the Utility Requirement" ("Guidelines") (copy enclosed). These "Guidelines" included an analysis of "Legal Precedent Governing Utility Rejections." Applicant respectfully submits that the pending 101 rejection is unquestionably mooted by the weight of precedent, as interpreted by the PTO in the Guidelines.

The PTO's analysis of legal precedent and the proposed Guidelines provide that: "An applicant's assertion of utility creates a presumption of utility that will be sufficient, *in most cases*, to satisfy the utility requirement of 35 U.S.C. § 101." p. 238. "Courts have repeatedly found that the mere *identification* of a pharmacological activity of a compound relevant to an asserted pharmacological use provides an "immediate benefit to the public" and thus satisfies § 101." p. 236. "[A]s the Federal Circuit has stated, '[t]o violate § 101 the claimed device must be *totally incapable of achieving a useful result.*'" p. 236. "If the applicant has asserted that the claimed invention is useful for any particular purpose and that assertion would be considered credible by a person of ordinary skill in the art, the Examiner should not impose a rejection based on § 101."

Guidelines, § B(2)(a), p. 234. "[If] one of ordinary skill in the art would consider the assertions of the applicant to have any reasonable scientific basis...they should not be challenged as not being credible. Only where...the assertion is 'incredible in view of contemporary knowledge'...should the Examiner challenge the assertion as not being credible." p. 239. "[E]vidence (of utility) will be sufficient if, considered as a whole, it leads a person of ordinary skill to conclude that the asserted utility is more likely than not true." p. 240. "Data from *in vitro* and animal testing is generally sufficient to support therapeutic utility." p. 240. "There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention relative to treatment of human disorders, even with respect to situations where no art-recognized animal models exist..." p. 242. (numerous case law citations omitted; see enclosed text of Guidelines)

Under the applicable precedent and the proposed Guidelines, the Applicant's assertion that the claimed invention is useful for the asserted purpose - as a vaccine - created a "presumption of utility." It is the Examiner's burden to establish that, more likely than not, the asserted utility is *not* true. The Examiner has previously admitted that anti-Recognin antibodies have anti-cancer cell properties *in vitro*. She has also noted that the presence of these antibodies is quantitatively associated with greater survival in human cancer patients. Clearly, then, the Examiner's own admissions, when combined with the presumption of utility, make it more likely than not that the asserted utility *is* true. The Applicant's assertion of utility has a "reasonable scientific basis" and would be "considered credible by a

person of ordinary skill in the art" The Examiner has pointed to no experimental evidence that shows that the invention does not work as claimed. In contrast, the above admissions by the Examiner and the data and arguments made of record here and in previous responses by Applicant are clear evidence that it does work.

Applicant thus respectfully requests the withdrawal of the § 101 rejection.

The § 112 rejection was improper.

In the February 22, 1995 Advisory Action, the Examiner maintained his rejection of claims 1 and 2 under § 112, first paragraph, as failing to adequately teach how to make and/or use the invention.

It is the Examiner's burden to make a *prima facie* showing that the subject matter claimed is not enabled. In re Marzocchi & Horton, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). The limitations on how the Patent Office may proceed in assessing the sufficiency of a disclosure have been clearly delineated:

As a matter of Patent Office practice, then, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.

In re Marzocchi & Horton, 169 U.S.P.Q. 367, 369-370 (C.C.P.A. 1971). See also In Re Dinh-Nguyen and Sterhagen, 181 U.S.P.Q. 46 (C.C.P.A. 1974) and In Re Bowen, 181 U.S.P.Q. 48 (C.C.P.A. 1974).

The Applicant described in example 8 of the application that malignin, Recognin L or Recognin M can be administered subcutaneously to individual humans or animals in doses of approximately 1 mg or more. The Applicant also stated that the level of anti-Recognin will increase approximately 10 days after the first administration of vaccine, that booster shots should be administered at 10 days and at 20 days after the initial immunization, and that about 30 days after the first dose the anti-Recognin response should be at a maximum.

The Applicant has fully taught a person of ordinary skill how to practice his invention; such a person need only follow the steps described above and throughout the application. These teachings by the Applicant "of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth" of the description.

However, the thrust of the Examiner's purported § 112 rejection is not that the Applicant has not described how to practice his invention, but rather that the Examiner doubts that the above sequence of steps will actually result in protective immunity.

Because patients diagnosed with cancer already have increased serum levels of anti-Recognin antibody, as disclosed in the specification, it is not predictable whether enhancing those antibody levels by administering an anti-Recognin vaccine would be effective in treating the cancer. In addition Stevenson discloses

that vaccination against cancer poses other problems such as the selection of a suitable adjuvant for use in humans. **Therefore, in the absence of clinical data or an appropriate animal model, one of ordinary skill in the art could not predict if the claimed vaccine would sufficiently increase the levels of anti-Recognin antibodies to prevent or treat cancer in humans.**

Office Action dated 12/22/1993 (Paper # 6) at 5 (emphasis added). This rejection was maintained in the Office Action dated 9/12/1994 (Paper # 10) and in the Advisory Action of 2/22/95 (Paper # 14). In other words, the Examiner suggests that the invention may be inoperable.

However, this is really a utility argument, not an enablement argument. It seems that the Examiner is implying that in order to satisfy the enablement requirement Applicant must provide a working example of protective immunity induced by Recognins. However, working examples are not required to enable subject matter. In re Borkowski, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970) ("a specification need not contain a working example if the invention is otherwise disclosed").

Thus, the Applicant does not have the burden of establishing a working example of a group of humans vaccinated with a Recognin in order to enable the invention. Rather, it is the Examiner's burden to show that a person of ordinary skill who follows the Applicant's clearly delineated instructions will fail. Applicant respectfully submits that the Examiner has not met this burden. The fact that actuarial studies have shown, at probability levels below  $p < 0.0001$ , that length of survival of known cancer patients correlates with serum level of anti-Recognin, together with the *in vitro*

evidence of the cytotoxicity to cancer cells of anti-Recognin antibodies (March 17, 1994 Response at 5), is compelling evidence that Applicants disclosure is enabling. The Examiner's rejection improperly seeks to contradict this evidence, not with evidence, but with untested hypothetical conjectures.

Conclusion

In summary, for the reasons discussed above, the Applicant respectfully requests that the §§ 101 and 112 rejections be withdrawn, and the allowance of the pending claims.

Sincerely,

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